

### Remarks

Claims 1-13 are pending in this application. No new matter has been added as a result of the above amendments.

### Drawings

An appropriate amendment has been made to include the sequence identity for figure 1.

### Rejection of claims 1-3 and 6-8 are rejected under 35 USC 102(e)

Claims 1-3 and 6-8 are rejected under 35 USC 102(e) as being anticipated by Short (US Publication 2002/0006620, filed January 17, 2002). Applicant respectfully disagrees.

The Examiner asserts that "Short teaches a method for identifying one or more complexes from a library of complexes where the complex or complexes are selected for their ability to perform a preselected or desired function on a target molecule or by having a preselected structure." The Examiner continues, "Short teaches that repeated cycles of selection for the highest affinity and error-prone PCR can lead to increased diversity and oligomers with an even greater affinity. Short specifically teaches that a library of morphatides is prepared, *screening the library of morphatides of the first step by contacting, binding, or associating the morphatides with one or more suitable target molecules* upon which a morphatide performs a preselected or desired function or to which a morphatide binds or associates and separating the morphatides performing the binding or associating through the preselected structure from the library of morphatides and target molecules, thereby identifying one or more complexes from a library." [*italics added for emphasis*]

Section 102 of Title 35 provides the novelty requirements for patentability. In order for a prior art reference to anticipate a claim it must teach each and every element of that claim. M.P.E.P. §2131. The Court of Appeals for the Federal Circuit states: "[a] claim is anticipated only if each and every element as set forth in the claim is found,

either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628 (CAFC, 1987).

The presently claimed invention discloses a method of making replicatable RNA templates which have a high affinity to a heterogenous target through iterative steps. Unlike Short, the presently claimed invention employs one or more heterogenous target molecules used to screen the RNA templates - importantly, these target molecules are covalently linked to a polymerase. For example, the Examiner is directed to page 4 the first full paragraph - beginning on line 23 it reads, *sic* "[t]he target is bound to or incorporated in one or more subunits [*referring to the subunits of the polymerase*]."

Continuing on line 24, ... the target is a protein the nucleic acid encoding such target is cloned into the nucleic acid encoding such subunit [*again referring to a subunit of the polymerase*] and expressed as part of such subunit." So unlike Short, the target in the claimed invention refers to a molecule that is actually a part of the polymerase, whereas Short discloses a target molecule that is a separate entity that is explored by and separate from one or more morphatides. Claim 1 has been amended to more accurately reflect the present invention by including this limitation.

The selection for the claimed invention is based upon affinity between an RNA replicatable template (*e.g.*, RNA) and the heterogenous target (*e.g.*, a nucleic acid). In Short, the selection process actually involves selecting morphatides based on their affinity with a target, wherein the target is a receptor, antibody, lectin, polysaccharide, cell, etc (see ¶ 0076 of Short). This discussion demonstrates another distinction between the presently claimed invention and Short. Specifically, the target molecule in the instant invention as claimed is a nucleic acid, whereas the target in Short appears to be entities other than nucleic acids, again reference is made to paragraph 0076 of Short.

Further, Short fails to teach the use of QB replicase as is claimed in the present invention.

Short fails to teach each and every element of the claimed invention, thus, it can not serve as a 102(e) prior art reference defeating the novelty of the present invention as claimed. Therefore, Applicant respectfully request reconsideration and withdrawal of the present rejection.

**Rejection of claims 4-5 and 10-13 are rejected under 35 USC 103(a)**

Claims 4-5 and 10-13 are rejected under 35 USC 103(a) as being unpatentable over Short in view of Rohde *et al.* (J. Mol. Biol. v 249, pp754-62, 1995). Applicant respectfully disagrees.

The Examiner essentially repeats her assertions with respect to the teachings of Short above. However, the Examiner adroitly points out that Short fails to teach the use of QB replicase. Applicant agrees that Short fails to teach this element. The Examiner contends however that Rohde teaches the use of QB replicase. Further, the Examiner asserts that it would have been *prima facie* obvious to one of ordinary skill at the time the invention was made to have modified the selection method of Short to include the RNA polymerase QB as taught by Rohde. Applicant respectfully disagrees.

In order to establish a *prima facie* case of obviousness, "there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references) must teach or suggest all of the claim limitations." M.P.E.P. §2143, see also, *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Moreover, it is axiomatic in patent law that if an independent claim defines allowable subject matter then the claims depending therefrom also define allowable subject matter. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988), and *Hartness International, Inc. v. Simplimatic Engineering Co.*, 819 F.2d 1100, 1108, 2

USPQ2d 1826, 1831 (Fed. Cir. 1987). Given that the rejected claims depend from base claims and those independent claims define allowable subject matter, then the claims at issue must necessarily define allowable subject matter. The reasons for allowability of the base claims are set forth above.

The deficiencies of Short are not remedied by Rohde. For example, in the presently claimed invention the target is actually bound to or incorporated within the polymerase. This element is completely absent in Short. (See above for further treatment of this issue.) There is no teaching or suggestion in Rohde as to this element of the present invention. Therefore, even if it were correct to use Short in combination with Rohde, the combination fails to recite, teach or suggest this element of the presently claimed invention, thus, the argument for *prima facie* obvious fails.

There is no suggestion or motivation provided by either Short or Rohde to combine these references. Again, even if there were such motivation, the combination would not arrive at the presently claimed invention. Failure to provide motivation together with a reasonable expectation of success vitiates a *prima facie* obvious argument employing these two references. Therefore, Applicant respectfully requests reconsideration and withdrawal of the present rejection.

Applicant believes that his claimed invention is now in condition for allowance and respectfully requests that the Examiner issue a Notice of Allowance. The Examiner is invited to call the undersigned attorney at (617) 854-4237 should she determine that a telephonic interview would expedite prosecution of this case.

Respectfully submitted,



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